Case law of article 88 of directive 2001/83 of OTC product

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Public Declaration of transparency/interests*

The view and opinions expressed are those of the individual presenter and should not be attributed to AIFA

Interests in pharmaceutical industry	NO	Current	From 0 to 3 previous years	Over 3 preavious years
DIRECT INTERESTS:				
1.1 Employment with a company: pharmaceutical company in an executive role	☒	☐	☐	☐ mandatory
1.2 Employment with a company: in a lead role in the development of a medicinal product	☒	☐	☐	☐ mandatory
1.3 Employment with a company: other activities	☒	☐	☐	☐ optional
2. Consultancy for a company	☒	☐	☐	☐ optional
3. Strategic advisory role for a company	☒	☐	☐	☐ optional
4. Financial interests	☒	☐	☐	☐ optional
5. Ownership of a patent	☒	☐	☐	☐ optional
INDIRECT INTERESTS:				
6. Principal investigator	☒	☐	☐	☐ optional
7. Investigator	☒	☐	☐	☐ optional
8. Grant or other funding	☒	☐	☐	☐ optional
9. Family members interests	☒	☐	☐	☐ optional

*Carla Cantelmo, in accordance with the Conflict of Interest Regulations approved by AIFA Board of Directors (25.03.2015) and published on the Official Journal of 15.05.2015 according to EMA policy /626261/2014 on the handling of the conflicts of interest for scientific committee members and experts.

N.B. < I am not receiving any compensation>

Classification of OTC product: a residual rule

- According to Article 70 of directive 2001/83, a medicinal product may be subject or not subject to medical prescription according to the criteria laid down in Article 71 (1).
- According to Article 72, MPs which do not meet the criteria listed in Article 71 shall not be subject to medical prescription.
- In Italy, according to Article 87 of Legislative decree no. 219/2006 (implementing directive 2001/83), MPs not subject to medical prescription are divided into two categories:

➢ O.T.C. medicinal products,

➢ Other MPs not subject to medical prescription, called “S.O.P.”

Distinction between O.T.C. and S.O.P.

- Distinction between O.T.C. and S.O.P. is relevant in Italy not only for their supply and reimbursement to the National Health System, but also for advertising, which was admitted only for O.T.C. and not for S.O.P. on the basis of Law no. 537/1993 (concerning the reimbursement classes) and Legislative decree no. 219/2006.
- MPs not subject to medical prescription admitted to the advertising to the general public are classified in class of reimbursement "C-*bis*" as O.T.C.
- Other MPs not subject to medical prescription (S.O.P.) may be reimbursed or not on the basis of their essentiality for the National Health System and must not be advertised.

Summary of the question

- The above mentioned distinction has been recently contested in two different Court Cases proposed against AIFA and the Italian Ministry of Health.
- The Italian Administrative Court (T.A.R.) has annulled the decision of the Ministry of Health to forbid the advertising to the general public of a MP classified as S.O.P. (Case law 1) and the AIFA decision to reject the application for the classification of an herbal MP as O.T.C. (Case law 2).
- This sentences have been confirmed by the Administrative Court of Appeal (Council of State), who has rejected the proposed appeals.

Case law 1

- Chefaro Pharma asked the Administrative Court to annul the decision of Ministry of Health to refuse the autorisation to advertise at the general public the MP «Bronchodual». The application was rejected on the basis that Bronchodual was not classified as O.T.C. and so it couldn't be advertised to the general public according to law no. 537/1993.
- According to the Ministry of Health the advertising of a S.O.P. could prejudice the public health causing an increase of sale outside the control of the physician and the pharmacist.

Decision TAR Lazio no. 7539/16

- The Administrative Court argued that both S.O.P. and O.T.C. shall be considered on the same floor for the public health and for this reason their distinction for the purpose of advertising to the general public is not justified. The provisions forbidding the advertising to the general public of MPs contained at article 115 of the Legislative decree no. 219/2006, implementing article 88 of the directive 2001/83, cannot be referred to medicinal products not subject to medical prescription and not classified as O.T.C.
- The above mentioned rules prevail on the previous dispositions of Law no. 537/1993 which restricted the advertising to O.T.C. only.

Decision CDS no. 2217/17

- After the appeal, the Council of State confirmed the referred decision, clarifying that the distinction between S.O.P. and O.T.C. introduced by the Italian legislation is still relevant just for the purpose of their reimbursement, but not to limit the advertising to the general public.

- The interpretation of article 88 of directive 2001/83 - according to which while advertising to the general public is always forbidden for MPs subject to medical prescription, MSs may introduce differences within MPs not subject to prescription in order to limit the advertising - cannot be shared.

Decision CDS no. 2217/17

- According to the Council of State, in the light of Article 114 of TFUE and the scope of the harmonization of laws and procedure, all the provisions which introduce limits and restrictions must be interpreted restrictively, so that in case the law does not provide anything, it shall be granted the “freedom of movement of goods”.
- Article 88 of directive – that establishes a general ban of advertising for determined MPs – must be interpreted in the meaning that advertising is always permitted when not expressly forbidden. A legislation who would introduce more limits without a specific necessity, could infringe Article 88 of the directive.

Decision CDS no. 2217/17

- The Council of State recovered an indirect confirmation of that interpretation from the wording of "*considerando*" 43 of directive, where it recognizes that there are disparities between the measures adopted by MSs concerning the advertising of medicinal products, which are likely to have an impact on the functioning of the internal market.
- The solution adopted by directive 2001/83 is to extend to all media the advertising ban of MPs available only on prescription (*considerando* 44).

Decision CDS no. 2217/17

- Under another profile, the Council of State considered that a different grade of dangerousness between MPs classified as S.O.P. or O.T.C., couldn't justify the extension of a generalized ban, but could legitimate different measures when releasing the authorization to the advertising, on the basis of *considerando* 45: "*advertising to the general public, even of non-prescription medicinal products, could affect public health, were it to be excessive and ill-considered. Advertising of medicinal products to the general public, where it is permitted, ought therefore to satisfy certain essential criteria which ought to be defined*".

Case law 2

- Willmar Schwabe Gmbh & Co K.G asked the Administrative Court to annul the decision of AIFA not to authorize the changing in the classification of the herbal medicinal product «Vitango» form S.O.P. to O.T.C.
- AIFA rejected this application on the basis of the autorised indications of the MP, that were considered not compatible both with the classification as O.T.C. and promotion to the general public. On the contrary, the classification as S.O.P. better satisfied the public health, as the MP shall be delivered in a pharmacy under the pharmacist control.

Decision TAR Lazio no. 9412/2016

- The Administrative Court annulled the contested decision.
- In T.A.R. opinion, herbal MPs shall be classified as O.T.C. when their efficacy and safety have been demonstrated by evidence and practice.
- Moreover, it shall be considered that the peculiar therapeutic effect of Vitango and the indication contained in the FI to consult a physician in case of persistent diseases, are sufficient to minimize the risk for patients.

Decision CDS no. 3737/2017

- After the appeal, the Council of State confirmed the referred decision, on the basis of the principle stated in its previous decision no. 2217/17.
- The CDS confirmed that the distinction between S.O.P. and O.T.C. is relevant for the reimbursement system only, but not for the advertising.
- In particular, the criteria laid down in the ministerial disposition no. 13/1997, used for the classification of O.T.C. products, correspond to those provided for herbal MPs by Article 16a of directive 2001/83.

Final considerations

- Although the referred interpretation of the Court couldn't be considered as legally binding, it would probably influence the future decisions of the competent Italian Authorities about classification and advertising of non-prescription MPs.
- It would be interesting to launch a survey on the interpretation and application of Article 88 of directive 2001/83 in other MSs.

Questions

- Do you agree that according to Article 88 of directive, advertising is always permitted when not expressly forbidden?
- Did you distinguish in your legislation between non-prescription MPs for the purpose of advertising?
- Did you adopt essential criteria for the advertising of O.T.C. medicinal products in order to protect public health?